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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

ALEX M. AZAR II, in his official
capacity as the Secretary of the United
States Department of Health and
Human Services,

Defendant.

No. 2:20-cv-00374-SMJ

PLAINTIFF'S REPLY IN SUPPORT
OF MOTION FOR SUMMARY
JUDGMENT

Mr. Olsen's motion should be granted. The Secretary's opposition did not
contest that:

- 1) the Secretary was required to comply with the notice and comment
provisions of 42 U.S.C. § 1395hh prior to issuing CMS 1682-R;

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- 2) the Secretary did not comply with the notice and comment provisions of CMS 1682-R prior to issuing it;
- 3) 42 U.S.C. § 1395hh(a)(2) precludes any policy not issued in accordance with § 1395hh's provisions from taking effect ("No rule ... shall take effect unless it is promulgated ...");
- 4) Mr. Olsen's claim was denied based on alleged non-compliance with the illegally issued CMS 1682-R;
- 5) both the ALJ and the Medicare Appeals Council lack the power/authority to disregard or overturn CMS 1682-R and were bound to follow it; and
- 6) any protest by Mr. Olsen that CMS 1682-R issued illegally would have been futile before the ALJ and the MAC because they lack the power/authority to not apply CMS 1682-R.

Thus, the only non-remedy issue the Court need decide is whether a party waives an argument not presented to an administrative body, when the body lacks the power or jurisdiction to decide it. The Ninth Circuit has repeatedly held that there is no waiver in such circumstances. *See, e.g., Reid v. Engen*, 765 F.2d 1457, 1460-61 (9th Cir. 1985) ("We may decide an issue not raised in an agency action if the agency lacked either the power or the jurisdiction to decide it."). Clearly,

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1 parties are not required to engage in the futile act of presenting arguments to
2 tribunals that cannot address them on pain of waiver.
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4 The Secretary's argument that this Court cannot afford Mr. Olsen the relief
5 requested is likewise without merit.
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7 To be clear, while there are also other bases for reversing the Secretary's
8 denial in Mr. Olsen's case, Mr. Olsen seeks a finding that CMS 1682-R issued
9 illegally because the Secretary continues to use that Ruling to deny thousands of
10 claims for CGM coverage each year. Thus, a decision finding that CMS 1682-R
11 issued illegally will benefit not just Mr. Olsen but other diabetics similarly
12 situated.¹
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19 ¹ Conversely, it appears that the Secretary hopes to avoid such a ruling and to
20 continue to rely on the illegally issued Ruling to deny CGM coverage. Plaintiff
21 points out that Defendant has filed two identical briefs as both "Response" to
22 Plaintiff's Motion for Summary Judgment and as "Cross Motion" for summary
23 judgment, both of which raise issues and arguments outside the scope of Plaintiff's
24 motion.
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DISCUSSION

Ancillary Matters

Mr. Olsen addresses a few ancillary matters to avoid confusion, especially as it relates to issues that may arise in the future. Mr. Olsen contests the Secretary's characterization that the denial of Mr. Olsen's claim was based on the alleged accuracy of one device versus another. ECF No. 27 at 1 – 2. Instead, Mr. Olsen's claim was denied on the grounds that a continuous glucose monitor is not "durable medical equipment" because it is not "primarily and customarily used to serve a medical purpose" as defined in CMS 1682-R. That is the basis on which Mr. Olsen's request for "redetermination", *e.g.*, was denied and the basis on which the MAC denied Mr. Olsen's claim. ECF No. 22 at 9 - 10.

As indicated in Mr. Olsen's opening papers, four district courts have already considered, and rejected, the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose." *Id.* at 5 – 6. Each of those courts rejected the idea that the phrase "primarily and customarily used to serve a medical purpose" is ambiguous and, even assuming that it was, that the Secretary's construction of that phrase as excluding CGMs such as Mr. Olsen's was reasonable. *Id.*



At the time Mr. Olsen filed his opening papers, three of those courts had already held that the Secretary's position lacked "substantial justification" and ordered the Secretary to pay the plaintiffs' legal fees for having to litigate the issue. *Id.* Since Mr. Olsen filed his opening papers, the fourth district court also found that the Secretary's position lacked "substantial justification" and also ordered the Secretary to pay the plaintiff's legal fees for having to litigate the issue. *See Zieroth v. Azar*, Case No. 20-cv-00172-MMC, 2020 WL 7075629 (U.S. Dist. N.D. CA.) (slip opinion).

Mr. Olsen Did Not Waive Objection to CMS 1682-R

With regard to the illegal issuance of CMS 1682-R and illegal application of CMS 1682-R to Mr. Olsen, the entirety of the Secretary's opposition is found on pages 9 and 10 of the Secretary's brief. As noted, the Secretary's defense is limited to the issue of whether Mr. Olsen waived the illegality of CMS 1682-R by not objecting on that ground before the ALJ and/or MAC, when neither body has the power or jurisdiction to decide that issue and were both bound to follow it.

As indicated, the Ninth Circuit has repeatedly held that there is no waiver in these circumstances. *See, e.g., GTE California, Inc. v. F.C.C.*, 39 F.3d 940, 949 (9th Cir. 1994) ("GTECA was not required to do a futile act."); *Marathon Oil Co. v. U.S.*, 807 F.2d 759, 767-68 (9th Cir. 1985); *Reid v. Engen*, 765 F.2d 1457, 1460-



61 (9th Cir. 1985) (“We may decide an issue not raised in an agency action if the agency lacked either the power or the jurisdiction to decide it.”).

Thus, Mr. Olsen may raise the illegality of CMS 1682-R before this Court. As shown, the Secretary failed to comply with the notice and comment provisions of 42 U.S.C. § 1395hh before issuing CMS 1682-R and, pursuant to § 1395hh, neither the Secretary nor this Court “shall” let it “take effect.” Accordingly, CMS 1682-R issued and was applied to Mr. Olsen illegally and the Secretary’s denial of Mr. Olsen’s claim on that basis should be reversed.

This Court Can Accord Mr. Olsen All the Relief Sought

In the event that this Court finds that CMS 1682-R issued illegally and that Mr. Olsen was not required to perform the futile act of objecting to the illegal issuance of CMS 1682-R before the ALJ or MAC, the Secretary contends that this Court should remand for further process before the Department. ECF No. 27 at 9 – 10.

This is merely a request that the Secretary be given an opportunity to violate his own regulations. As noted, CMS did not appear before ALJ. ECF No. 22 at 10. Accordingly, pursuant to 42 C.F.R. § 405.1110(c)(1), “the Council will limit its consideration of the ALJ’s ... action to those exceptions raised by CMS.” Here, CMS only sought review by the MAC based on the alleged misapplication



1 of CMS 1682-R. *Id.* Thus, rejecting Mr. Olsen's claim on any other basis would
2 violate the Secretary's own regulations. Accordingly, remand would be futile and,
3 pursuant to 42 U.S.C. 405(g) (fourth sentence) coverage should be ordered.
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5 The Secretary has repeatedly requested that district courts remand cases so
6 the Secretary can have an opportunity to violate his own regulations.
7 Consistently, the district courts have rejected this request. For example, in
8 *Maupin v. Azar*, 424 F.Supp.3d 830 (C.D. Cal. 2019), though the request for
9 review was limited to the issue reversed by the district court, the Secretary
10 requested a remand to consider other bases for denial. Because MAC review was
11 limited to the issues raised in CMS' exceptions and the only exception was on the
12 issue overturned by the court, the court rejected the Secretary's request and
13 ordered coverage. *Id.* at 838-39.
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18 Likewise in the present case, CMS' exceptions were limited to the issue of
19 alleged misapplication of CMS 1682-R. Thus, if the MAC were to consider any
20 other basis on which to reject Mr. Olsen's claim, that would violate the
21 Secretary's own regulations.
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CONCLUSION

For the reasons set forth above, the Court should hold that CMS 1682-R is invalid, reverse the Secretary's denial of Mr. Olsen's claim, and order the Secretary to cover Mr. Olsen's claim.

Dated this 21st day of December, 2020.

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By: s/ Casey M. Bruner

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PLAINTIFF'S REPLY IN SUPPORT
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CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of December 2020:

1. I caused to be electronically filed the foregoing PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT with the Clerk of the Court using the CM/ECF System which will send notification of such filing to the following:

James.Bickford@usdoj.gov

2. I hereby certify that I have caused to be mailed by United States Postal Service the foregoing document to the following non-CM/ECF participants at the addresses listed below:

Jeffrey Blumenfeld
Lowenstein Sandler LLP
2200 Pennsylvania Avenue, NW, Suite 500E
Washington, DC 20037

3. I hereby certify that I have mailed by United States Postal Service the foregoing document to the following CM/ECF participants at the address listed below: **None.**

4. I hereby certify that I have hand-delivered the foregoing document to the following participants at the addresses listed below: **None.**

s/ Casey M. Bruner

Casey M. Bruner, WSBA #50168

PLAINTIFF'S REPLY IN SUPPORT
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